

# Federal Register Notices Concerning MDUFMA

Updated through *Federal Register* of January 6, 2004

Date	Subject	Citation	Comment / Action Date
11/21/2002	Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures.  <ul style="list-style-type: none"> <li>1/10/2003 — Correction — A 510(k) submitted during FY 2003 is not eligible for a reduced small business fee. Fee for any 510(k) submitted during FY 2003 is \$2,187.</li> <li>1/22/2003 — Correction — Same intent.</li> </ul>	<a href="#">67 F.R. 70228</a>  <a href="#">68 F.R. 1469</a>  <a href="#">68 F.R. 3033</a>	—  —  —
2/4/2003	Establishment of a Public Docket.	<a href="#">68 F.R. 5643</a>	Any time.
2/10/2003	Request for comments on proposed information collection —MedWatch: The FDA Medical Products Reporting Program. (60-day notice.)  Section 202 of MDUFMA directs FDA to modify MedWatch forms to facilitate the reporting of information pertaining to reprocessed single-use devices.  Also see 4/29/2003 (submission to OMB) and 10/10/2003 (OMB approval).	<a href="#">68 F.R. 6752</a>	4/11/2003
2/25/2003	Medical Device User Fee Payment Procedures.	<a href="#">68 F.R. 8773</a>	—
2/26/2003	Request for comments on proposed information collection — Medical Device User Fee Cover Sheet; Form FDA 3601. (60-day notice.)  Also see 5/21/2003 (submission to OMB) and 8/25/2003 (OMB approval).	<a href="#">68 F.R. 8907</a>	4/28/2003
3/26/2003	Agency Emergency Processing Under OMB Review; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602).  Also see 4/28/2003 (OMB approval).	<a href="#">68 F.R. 14664</a>	4/25/2003
3/27/2003	Availability of Guidance — Fiscal Year 2003 MDUFMA Small Business Qualification Worksheet and Certification.  (This guidance is now obsolete; it was replaced by new guidance for FY 2004. The FY 2004 guidance is available at <a href="http://www.fda.gov/cdrh/mdufma/guidance/1225.pdf">www.fda.gov/cdrh/mdufma/guidance/1225.pdf</a> )	<a href="#">68 F.R. 14992</a>	Any time.

Date	Subject	Citation	Comment / Action Date
4/28/2003	OMB Approval of Information Collection; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602).  This approval expires 10/31/2003 (form will not be used after 9/30/2003; see 7/18/2003 for notice on replacement form).  Also see 3/26/2003 (emergency submission to OMB).	<a href="#">68 F.R. 22387</a>	—
4/28/2003	Agency Emergency Processing Under OMB Review; Inspection by Accredited Persons Under MDUFMA.  Also see 6/26/2003 (OMB approval).	<a href="#">68 F.R. 22388</a>	5/28/2003
4/28/2003	Availability of Guidance — Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria.  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/1200.pdf">www.fda.gov/cdrh/mdufma/guidance/1200.pdf</a>  Also see 11/6/2003 (list of accredited persons).	<a href="#">68 F.R. 22400</a>	Any time.
4/29/2003	Submission of proposed information collection to OMB — MedWatch: The FDA Medical Products Reporting Program.  Also see also 2/10/2003 (60-day notice) and 10/10/2003 (OMB approval).	<a href="#">68 F.R. 22716</a>	5/29/2003
4/30/2003	Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.  Provides list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k).  Also see 6/26/2003 (adding nonelectric biopsy forceps to the list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k).).	<a href="#">68 F.R. 23139</a>	Effective 4/30/2003; 510(k)s due 7/30/2004; validation data for devices already cleared under 510(k) due 1/30/2004

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5/21/2003	Submission of proposed information collection to OMB — Medical Device User Fee Cover Sheet; Form FDA 3601.  Also see 2/26/2003 (60-day notice) and 8/25/2003 (OMB approval).	<a href="#">68 F.R. 27818</a>	6/30/2003
6/3/2003	Availability of Guidance — Pediatric Expertise for Advisory Panels.  This guidance is available at — <a href="http://www.fda.gov/cdrh/ode/guidance/1208.pdf">www.fda.gov/cdrh/ode/guidance/1208.pdf</a>	<a href="#">68 F.R. 33166</a>	Any time.
6/23/2003	Availability of Draft Guidance — Compliance with Section 301 of MDUFMA – Identification of Manufacturer of Medical Devices.  This guidance is available at — <a href="http://www.fda.gov/cdrh/comp/guidance/1217.pdf">www.fda.gov/cdrh/comp/guidance/1217.pdf</a>	<a href="#">68 F.R. 37161</a>	9/22/2003
6/26/2003	OMB Approval of Information Collection; Inspection by Accredited Persons Program Under MDUFMA.  This approval expires 9/30/2003.  Also see 4/28/2003 (emergency submission to OMB).	<a href="#">68 F.R. 38065</a>	—
6/26/2003	Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.  Adds nonelectric biopsy forceps to the 4/30/2003 list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Also clarifies deadline dates shown in 4/30/2003 notice.  Also see 4/30/2003 (original list of critical reprocessed single-use devices).	<a href="#">68 F.R. 38071</a>	Effective 6/26/2003; 510(k)s due 9/27/2004.
7/8/2003	Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices.  Also see 8/28/2003 (OMB approval).	<a href="#">68 F.R. 40676</a>	8/7/2003
	• 7/23/2003 — Correction — Corrects OMB contact information.	<a href="#">68 F.R. 43534</a>	—
	• 8/20/2003 — Correction — Corrects docket number	<a href="#">68 F.R. 50155</a>	—

Date	Subject	Citation	Comment / Action Date
7/8/2003	Availability of Guidance — Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices.  This guidance is available at — <a href="http://www.fda.gov/cdrh/ode/guidance/1216.pdf">www.fda.gov/cdrh/ode/guidance/1216.pdf</a>  • 7/23/2003 — Correction — Corrects docket number.	<a href="#">68 F.R. 40679</a>  <a href="#">68 F.R. 43538</a>	Any time.  —
7/10/2003	Request for comments on proposed information collection — Inspection by Accredited Persons Program Under MDUFMA. (60-day notice.)  Previously-approved information collection approval expires 9/30/2003; see 6/26/2003.  Also see 10/8/2003 (submission to OMB) and 12/9/2003 (OMB approval).	<a href="#">68 F.R. 41160</a>	9/8/2003
7/18/2003	Request for comments on proposed information collection — MDUFMA Small Business Qualification Certification (Form FDA 3602). (60-day notice.)  Revised version for use during FY 2004.  Also see 10/10/2003 (submission to OMB).	<a href="#">68 F.R. 42742</a>	9/16/2003
7/24/2003	Availability of Draft Guidance — Premarket Assessment of Pediatric Medical Devices.  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/1220.pdf">www.fda.gov/cdrh/mdufma/guidance/1220.pdf</a>	<a href="#">68 F.R. 43729</a>	10/23/2003
8/1/2003	Establishment of Medical Device User Fee Rates for Fiscal Year 2004.	<a href="#">68 F.R. 45246</a>	—
8/25/2003	OMB Approval of Information Collection; Medical Device User Fee Cover Sheet (Form FDA 3601).  Approval expires 8/31/2006.  Also see 2/26/2003 (60-day notice) and 5/21/2003 (submission to OMB).	<a href="#">68 F.R. 51023</a>	—

Date	Subject	Citation	Comment / Action Date
8/28/2003	OMB Approval of Information Collection; Submission of Validation Data for Reprocessed Single-Use Devices.  Approval expires 1/31/2004.  Also see 7/8/2003 (emergency submission to OMB).	68 F.R. 51788	—
9/29/2003	Notice of first Annual Stakeholder Meeting on Implementation of MDUFMA, to be held December 3, 2003.	68 F.R. 55967	Register to attend or listen (via call-in line) by 11/3/2003; indicate intent to speak and provide topic abstract by 11/3/2003.
10/8/2003	Submission of proposed information collection to OMB — Inspection by Accredited Persons Program Under MDUFMA.  Also see also 7/10/2003 (60-day notice) and 12/9/2003 (OMB approval).	68 F.R. 58113	11/7/2003
10/10/2003	Submission of proposed information collection to OMB — MDUFMA Small Business Qualification Certification (Form FDA 3602).  Revised version for use during FY 2004.  Also see 7/18/2003 (60-day notice).  ★ <i>Approved by OMB 12/17/2003; approval expires 12/31/2006. FDA will soon publish a Federal Register notice announcing this approval.</i>	68 F.R. 58690	11/10/2003
10/10/2003	OMB Approval of Information Collection; MedWatch Medical Products Reporting Program.  Approval expires March 31, 2005.  Also see also 2/10/2003 (60-day notice) and 4/29/2003 (submission to OMB).	68 F.R. 58691	—  Existing MedWatch forms may be used for the next 6 months (though 4/6/2004).
11/3/2003	Availability of Guidance — Premarket Approval Modular Review.  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/835.pdf">www.fda.gov/cdrh/mdufma/guidance/835.pdf</a>	68 F.R. 62298	Any time.

Date	Subject	Citation	Comment / Action Date
11/6/2003	Availability of list of persons accredited to conduct Quality Systems / GMP inspections under MDUFMA.  Also see 4/28/2003 (Availability of Guidance — Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria).	68 F.R. 62811	—
11/24/2003	Availability of Guidance — User Fees and Refunds for Premarket Approval Applications.  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/1224.pdf">www.fda.gov/cdrh/mdufma/guidance/1224.pdf</a>	68 F.R. 65940	Any time.
11/26/2003	Availability of Guidance — Bundling Multiple Devices or Multiple Indications in a Single Submission.  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/1215.pdf">www.fda.gov/cdrh/mdufma/guidance/1215.pdf</a>	68 F.R. 66461	Any time.
11/26/2003	Availability of Guidance — Expedited Review of Premarket Submissions for Devices  This guidance is available at — <a href="http://www.fda.gov/cdrh/mdufma/guidance/108.pdf">www.fda.gov/cdrh/mdufma/guidance/108.pdf</a>	68 F.R. 66463	Any time.
12/9/2003	OMB Approval of Information Collection; Inspection by Accredited Persons Program Under MDUFMA.  Approval expires November 30, 2006.  Also see also 7/10/2003 (60-day notice) and 10/8/2003 (submission to OMB).	68 F.R. 68632	Any time.

#### Additional information —

A complete list of all of FDA's MDUFMA guidance documents, including those not announced in the *Federal Register*, is available at —

[www.fda.gov/cdrh/mdufma/guidance](http://www.fda.gov/cdrh/mdufma/guidance)

Each guidance document is available in plain text (html) and portable document format (pdf).

